

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/660,112
				Filing Date	September 10, 2003
				First Named Inventor	Luskey, Kenneth L.
				Art Unit	1614
Examiner Name	Cook, Rebecca				
Sheet	2	of	6	Attorney Docket Number	016325-003721US

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
W	27	GB	1,403,309		08-20-1975	Merck & Co. Inc.		<input type="checkbox"/>
W	28	WO	00/74666	A2	12-14-2000	Metabolex, Inc. et al.		<input type="checkbox"/>
W	29	WO	02/44113	A2	06-06-2002	Metabolex, Inc.		<input type="checkbox"/>
W	30	WO	04/112774	A1	12-29-2004	Metabolex, Inc.		<input type="checkbox"/>

Examiner Signature	<i>RCook</i>	Date Considered	<i>06/22/05</i>
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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/382,485 10/660112
				Filing Date	March 4, 2003
				First Named Inventor	Luskey, Kenneth L.
				Art Unit	1614
				Examiner Name	Cook, Rebecca
Sheet	3	of	6	Attorney Docket Number	016325-003740US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
A	31	ARONOW, W.S. et al., "Halofenate: An Effective Hypolipemia- and Hypouricemia-Inducing Drug," <i>Current Therapeutic Research</i> , 15:902-906 (1973)	
✓	32	ARONOW, W.S. et al., <i>Clin. Pharmacol. Ther.</i> , 14:371-373 (1973)	
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n	34	BARRETT-CONNOR, "Epidemiology, Obesity, and Non-Insulin-Dependent Diabetes Mellitus," <i>Epidemiologic Review</i> , 11:172-181 (1989)	
n	35	BASSETT, D.R. et al., "Effects of halofenate and probenecid in serum lipids and uric acid in hyperlipidemic, hyperuricemic adults," <i>Clin. Pharmacol. Ther.</i> , 22:340-351 (1977)	
n	36	BELL et al., "Glucokinase Mutations, Insulin Secretion, and Diabetes Mellitus," <i>Annu. Rev. Physiol.</i> , 58:171-186 (1996)	
n	37	BERKOW and FLETCHER, "The Merck Manual of Diagnosis and Therapy - 15th Edition," pp 1069-1072, Merck Research Laboratories, N.J. (1987)	
n	38	BLUESTONE, R. et al., <i>Arthritis Rheum.</i> , 18:859-862 (1975)	
d	39	CHIASSON, J. et al., "The Efficacy of Acarbose in the Treatment of Patients with Non-Insulin-dependant Diabetes Mellitus," <i>Ann. Intern. Med.</i> , 121:928-935 (1994)	
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n	42	EDELMAN and HENRY, "Non-Insulin-Dependent Diabetes Mellitus," <i>Current Therapy in Endocrinology and Metabolism</i> , pp. 430-438 (1997)	
n	43	FAJANS et al., "Maturity Onset Diabetes of the Young (MODY)," <i>Diabetes Medicine</i> , 13:S90-S95 (1996)	
	44	FANELLI, G.M., Jr., <i>J. Pharmacol. Exp. Ther.</i>, 180:377-396 (1972)	
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Examiner Signature	<i>Rebecca</i>	Date Considered	6/22/05
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60438345 v1

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	40/382,185 10/660112		
		Filing Date	March 4, 2003		
		First Named Inventor	Luskey, Kenneth L.		
		Art Unit	1614		
		Examiner Name	Cook, Rebecca		
Sheet	4	of	6	Attorney Docket Number	016325-003740US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
in	47	FLIER, "Insulin Receptors and Insulin Resistance," <i>Ann. Rev. Med.</i> , 34:145-160 (1983)	
~	48	FRIEDBERG, "The Control of Insulin Resistant and Refractory Type II Diabetes Mellitus by Means of Halofenate-Sulfonylurea Combined Regimen," <i>Clinical Research</i> , 34:682A (1986)	
	49	GAVIN III et al., "Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus," <i>Diabetes Care</i>, 22:S5-S19 (1999)	
in	50	GOETZE, et al., "PPAR γ -Ligands Inhibit Migration Mediated by Multiple Chemoattractants in Vascular Smooth Muscle Cells," <i>Journal of Cardiovascular Pharmacology</i> , 33:798-806 (1999)	
in	51	HOWARD et al., "Lipoprotein Composition in Diabetes Mellitus," <i>Atherosclerosis</i> , 30:153-162 (1978)	
in	52	HUCKER et al., "Metabolism of a New Hypolipidemic Agent, 2-Acetamidoethyl (<i>p</i> -Chlorophenyl) (<i>m</i> -Trifluoromethylphenoxy)-Acetate (Halofenate) in the Rat, Dog, Rhesus Monkey and Man," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 179:359-371 (1971)	
in	53	HUTCHISON and WILKINSON, "The Uricosuric Action of Halofenate (MK-185) in Patients with Hyperuricemia or Uncomplicated Primary Gout and Hyperlipidemia," <i>Atherosclerosis</i> , 18:353-362 (1973)	
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in	55	JAIN, A. et al., <i>Clin. Pharmacol. Ther.</i> , 11:551-557 (1970)	
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✓	57	KELLER C. et al., <i>Arzneimittelforschung</i> , 28:2349-2352 (1976)	
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in	59	KNOWLER et al., "Obesity in the Pima Indians: Its magnitude and relationship with diabetes," <i>Am J Clin Nutr</i> , 53:1543S-1551S (1991)	
in	60	KOHL et al., "Improved Control of Non-insulin-dependent Diabetes Mellitus by Combined Halofenate and Chlorpropamide Therapy," <i>Diabetes Care</i> , 7:19-24 (1984)	
in	61	KREISBERG, R.A., "Hyperlipidemia," <i>Curr. Therapy Endocrin. Metabol.</i> , 6th Ed., pp. 509-519; Mosby-Yearbook, Inc. (1997)	
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Examiner Signature	<i>R. Cook</i>	Date Considered	<i>04/22/05</i>
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/382,186- 662/11 ✓		
		Filing Date	March 4, 2003		
		First Named Inventor	Luskey, Kenneth L.		
		Art Unit	1614		
		Examiner Name	Cook, Rebecca		
Sheet	5	of	6	Attorney Docket Number	016325-003740US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
u	64	LeROTH, D. et al. (eds.), Diabetes Mellitus, Lippincott-Raven Publishers, Philadelphia, PA U.S.A. (1966)	
u	65	LIN and LU, "Inhibition and Induction of Cytochrome P450 and the Clinical Implications, <i>Clin Pharmacokinet</i> , 35:361-390 (1998)	
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u	67	MAHLEY et al., "Disorders of Lipid Metabolism," <i>Williams Textbook of Endocrinology</i> , 1099-1153 (1998)	
	68	McMAHON, F.G. et al., "Some Effects of MK-185 on Lipid and Uric Acid Metabolism in Man", <i>Univ. Mich. Med. Center J.</i>, 36(4):247-248 (1970)	
u	69	MINERS and BIRKETT, "Cytochrome P450C9: an enzyme of major importance in human drug metabolism," <i>J Clin Pharmacol</i> , 45:525-538 (1998)	
u	70	MORGAN et al., "Hypolipidemic, uricosuric, and thyroxine-displacing effects of MK-185 (halofenate)," <i>Clin. Pharmacol. Therap.</i> , 12:517-524 (1971)	
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u	72	PELKONEN, et al., "Inhibition and induction of human cytochrome P450 (CYP) enzymes," <i>Xenobiotica</i> , 28:1203-1253 (1998)	
u	73	RAVENSCROFT, P.J. et al., <i>Clin. Pharmacol. Ther.</i> , 14:547-551 (1973)	
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u	75	REAVEN, "Pathophysiology of Insulin Resistance in Human Disease," <i>Physiological Reviews</i> , 75:473-486 (1995)	
u	76	RYAN, "The metabolic spectrum of halofenate," <i>Int. J. Clin. Pharmacol.</i> , 12:239-243 (1975)	
u	77	SCHAPPEL and EDWARDS, "Efficacy and Interactions of Oxandrolone, Halofenate and Clofibrate in a Factorial Study on Experimental Acute Nephrotic Hyperlipidemia," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 194:274-284 (1975)	
u	78	SCHOLOSSTEIN, L.H. et al., <i>J. Lab. Clin. Med.</i>, 82:412-418	
u	79	SIRTORI et al., "Clinical Evaluation of MK-185: A New Hypolipidemic Drug," <i>Lipids</i> , 7:96-99 (1971)	

Examiner Signature	RCook	Date Considered	6/22/05
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60438345 v1

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		Filing Date	March 4, 2003		
		First Named Inventor	Luskey, Kenneth L.		
		Art Unit	1614		
		Examiner Name	Cook, Rebecca		
Sheet	6	of	6	Attorney Docket Number	016325-003740US

NON PATENT LITERATURE DOCUMENTS			
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<i>A</i>	80	SKYLER, "Glucose Control in Type 2 Diabetes Mellitus," <i>Annals of Internal Medicine</i> , 127:837-838 (1997)	
<i>n</i>	81	STEINER et al., "A Comparative Review of the Adverse Effects of Treatments for Hyperlipidaemia," <i>Drug Safety</i> , 6:118-130 (1991)	
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<i>u</i>	83	The University of Michigan Medical Center Journal, 36:247-248 (1970)	
<i>u</i>	84	TRUST et al., "(Aryloxy)[p-(aryloxy)phenyl]- and (Aryloxy)[p-arylthio)phenyl]acetic Acids and Esters as Hypolipidemic Agents," <i>Journal of Medicinal Chemistry</i> , 22:1068-1074 (1979)	
	85	TURNER and GLAPHAM, "Insulin resistance, impaired glucose tolerance and non-insulin-dependent diabetes, pathologic mechanisms and treatment: Current status and therapeutic possibilities," <i>Progress in Drug Research</i>, 51:34-94 (1998)	
	86	VEDELL and PASSANANTI, "Differential Effects of Chronic Halofenate Administration on Drug Metabolism in Man," <i>Fed. Proc.</i>, 31:538 (1972)	
<i>u</i>	87	WILSON, J. et al., (ed.), "Disorders of Lipid Metabolism", Chapter 23 <i>Textbook of Endocrinology</i> , 9th Edition, W.B. Sanders Company, Philadelphia, PA U.S.A. (1998)	
<i>u</i>	88	WOLFRAM, G. et al., <i>Verh. Dtsch. Ges. Inn. Med.</i> , 79:1291-1293 (1973)	
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